

**510(k) Summary**

510(k) submitter: ..... 3M Deutschland GmbH  
 ESPE Platz  
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 Germany  
 Establishment Registration Number: 9611385

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 Date: ..... March 05, 2014

Trade Name: ..... Flash Penta™ MB Quick  
 Flash MB Quick

Common Name: ..... VPS impression material

Classification Name: ..... Impression material  
 (21 CFR 872.3660, product code ELW)

Predicate Devices ..... Flash Penta™ HB Q (K120438)  
 Flash Heavy Body Q (K120438)  
 Flash Regular Body Q (K120438)  
 Flash Light Body (K120438)

Description of Device

Flash Penta™ MB Quick and Flash MB Quick are addition type silicone impression materials of medium consistency. Flash Penta MB Quick is mixed in the Pentamix mixing device, while Flash MB Quick can be applied directly using the Garant™ dispenser. Both products are used in mono-phase technique and in one-step technique.

Indications for Use:

All types of impressions, e.g.:

- Crown, bridge, inlay, and onlay preparations
- Implants
- Orthodontic impressions

Substantial Equivalence

Information provided in this 510(k) submission shows that Flash Penta MB Quick and Flash MB Quick are substantially equivalent to the predicate devices Flash Penta HB Q, Flash Heavy Body Q, Flash Regular Body Q and Flash Light Body in terms of intended use, indications for use, composition and physical properties. A biocompatibility assessment was developed for Flash Penta MB Quick and Flash MB Quick using standard risk assessment techniques and consideration of FDA & internationally recognized guidelines. The conclusion of the assessment is that Flash Penta MB Quick and Flash MB Quick are safe for their intended use.

This 510(k) submission includes data from bench testing to evaluate the performance of Flash Penta MB Quick and Flash MB Quick compared to predicate devices Flash Penta HB Q, Flash Heavy Body Q, Flash Regular Body Q and Flash Light Body. The properties evaluated include consistency, total working time, detail reproduction, linear dimensional change, compatibility with gypsum type 3 / type 4, recovery from deformation and strain in compression.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

June 5, 2014

3M Deutschland GmbH  
Ruediger Franke  
Regulatory Affairs Specialist  
ESPE Platz  
Seefeld, Bavaria  
Germany 82229

Re: K140602  
Trade/Device Name: Flash Penta™ MB Quick, Flash MB Quick  
Regulation Number: 21 CFR 872.3660  
Regulation Name: Impression Material  
Regulatory Class: II  
Product Code: ELW  
Dated: March 5, 2014  
Received: March 10, 2014

Dear Mr. Franke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Mary S. Runner -S

Erin I. Keith, M.S.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

4 Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration <b>Indications for Use</b>	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement on last page.
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510(k) Number (if known)

K140602

Device Name

Flash Penta MB Quick and Flash MB Quick

Indications for Use (Describe)

All types of impressions, e.g.:

- Crown, bridge, inlay, and onlay preparations
- Implants
- Orthodontic impressions

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Sheena A. Green-S

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